

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/632,098 08/02/00 SHEPPARD

P 99-39

EXAMINER

HM22/0619

ROBYN ADAMS
ZYMOGENETICS
1201 EASTLAKE AVENUE EAST
SEATTLE WA 98102

PAK, Y

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/632,098

Applicant(s)

SHEPPARD ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-28 is/are pending in the application.
- 4a) Of the above claim(s) 5,8-12,14-18 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6,13,19 and 21-26 is/are rejected.
- 7) ☒ Claim(s) 27-28 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

A preliminary amendment filed on May 14, 2001, deleting claims 2 and 7 and adding claims 21-28, has been entered.

Claims 1, 3-6 and 8-28 are pending.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 8 is acknowledged. Claims 5, 8-12, 14-18 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claim Objections

Applicant is advised that should claims 22 and 24 be found allowable, claims 22 and 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-4, 6, 13, 19 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-4, 6, 13, 19 and 21-26 are drawn to a polypeptide comprising portions of SEQ ID NO:2 or 4 with no limitations to the function of the polypeptides. Also, claims 1, 3, 6 and 13 are drawn to polypeptides comprising of less than 10% of the whole structure of SEQ ID NO:2 and claims 4, 19, 21- 22 and 24 are drawn to polypeptides comprising of less than 60% of the whole structure of SEQ ID NO:2. A description of roughly over half and less than 10% of the whole structure of SEQ ID NO:2 amount to insufficient description of the structure of the polypeptides in these claims. Therefore, these claims are drawn to a large variable genus of polypeptides from any source having unknown activity or inactive variants and with an insufficient limitation on structure. Applicants only describe a Mammalian adhesion protease peptides (MAPP) of SEQ IDNO:2 and 4 from humans. The specification does not describe the function of all the polypeptide sequences derived or modified from SEQ ID NO:2 and 4 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Also, applicants do not describe which amino acids of SEQ ID NO:2 or 4 can be modified without effecting MAPP activity. Therefore, applicants fail to describe representative species by identifying characteristics or structural properties other than comprising of SEQ ID NO:2 or 4.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1, 3-4, 6, 13, 19 and 21-26.

Claims 1, 3-4, 6, 13, 19 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the MAPP of SEQ ID NO: 2 and 4, does not reasonably provide enablement for MAPP having different structures from SEQ ID NO:2 or 4 and polypeptides comprising portions of SEQ ID NO:2 or 4 with unknown activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches how to make and use the MAPP of SEQ ID NO:2 and 4. The specification does not teach how to make polypeptides comprising portions of SEQ ID NO:2 or 4 having MAPP activity. Applicants do not teach which amino acids of SEQ ID NO:2 or 4 can be modified without affecting the functional properties of the

polypeptide. Further, the specification does not teach how to use polypeptides comprising portions of SEQ ID NO:2 or 4 having unknown function. The function of a polypeptide can not be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does not establish: (A) regions of the MAPP structure which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to make polypeptides with structures different from SEQ ID NO:2 or 4 having MAPP activity and how to use polypeptides comprising portions of SEQ ID NO:2 or 4 having unknown

Art Unit: 1652

function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claims 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3173.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner


ELIZABETH SLOBODYANSKY, PH.D
PRIMARY EXAMINER

June 15, 2001